

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

GILEAD SCIENCES, INC. and
EMORY UNIVERSITY,

Plaintiffs,

v.

LUPIN LIMITED,

Defendant.

)
)
) Civil Action No. 14-cv-5352 (RJS) (AJP)
)
) **ECF Case**
)
) **LUPIN LIMITED’S ANSWER,**
) **SEPARATE DEFENSES, AND**
) **COUNTERCLAIMS TO**
) **PLAINTIFFS’ COMPLAINT**
)
)
) **Jury Trial Demanded**

Defendant Lupin Limited (“Lupin” or “Defendant”), by its undersigned attorneys, hereby answers the Complaint of Gilead Sciences, Inc. (“Gilead”), and Emory University (“Emory”) (collectively, “Plaintiffs”) for which every allegation not expressly admitted is denied, as follows:

Nature of Action

1. Paragraph 1 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that this action purports to allege patent infringement. Lupin denies all remaining allegations of Paragraph 1.

The Parties

2. Lupin lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 2 of the Complaint, and therefore denies all such allegations.

3. Lupin lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 3 of the Complaint, and therefore denies all such allegations.

4. As to the allegations in Paragraph 4 of the Complaint, Lupin admits that Lupin Ltd. is an Indian corporation, having its only place of business in India, including at 159 CST

Road, Kalina, Santacruz (E), Mumbai 400 098, India. Lupin denies all remaining allegations of Paragraph 4.

Jurisdiction and Venue

5. Paragraph 5 of the Complaint contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Lupin admits that the Complaint purports to allege patent infringement, and that subject matter jurisdiction is proper solely for claims asserted against Lupin under 35 U.S.C. § 271(e)(2)(A) only. Lupin denies all remaining allegations in Paragraph 5.

6. Paragraph 6 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, denied. Further answering, to conserve the resources of the parties and the Court and for purposes of judicial efficiency, Lupin does not contest personal jurisdiction in this judicial District solely for the limited purpose of this action only. Lupin denies all remaining allegations of Paragraph 6.

7. Paragraph 7 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, denied. .

8. Paragraph 8 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits only that Lupin develops and manufactures pharmaceutical products, including quality generic medicines. Lupin denies all remaining allegations of Paragraph 8.

9. Denied.

10. Denied.

11. Paragraph 11 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits only that Lupin develops and

manufactures pharmaceutical products, including quality generic medicines. Lupin denies all remaining allegations of Paragraph 11.

12. Denied.

13. Paragraph 13 of the Complaint contains legal conclusions to which no answer is required. To the extent that an answer is required, denied. Further answering, to conserve the resources of the parties and the Court and for purposes of judicial efficiency, Lupin does not contest personal jurisdiction in this judicial District solely for the limited purposes of this action only. Lupin denies the remaining allegations of Paragraph 13.

14. Paragraph 14 of the Complaint contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, denied. Further answering, to conserve the resources of the parties and the Court and for purposes of judicial efficiency, Lupin does not contest venue solely for the limited purposes of this action only.

Background

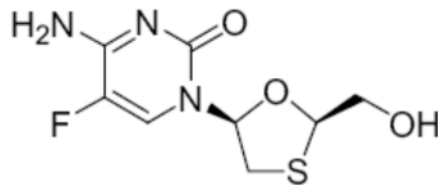
15. Paragraph 15 of the Complaint contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Lupin admits that the electronic version of the U.S. Food and Drug Administration's ("FDA") publication, *Approved Drug Products with Therapeutic Equivalence Evaluation* (commonly known as the "Orange Book"), identifies "GILEAD" as the purported "applicant" for New Drug Application ("NDA") No. 21-937 for Atripla[®] (efavirenz; emtricitabine; tenofovir disoproxil fumarate) tablets approved July 12, 2006. Lupin further admits that the current FDA-approved label for Atripla[®] (efavirenz; emtricitabine; tenofovir disoproxil fumarate) tablets states that it is "indicated for use alone as a complete regimen or in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults." Lupin lacks knowledge or information sufficient to form a belief

as to the truth of the remaining allegations in Paragraph 15, and therefore denies all such allegations.

16. Paragraph 16 of the Complaint contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Lupin admits that, according to the electronic records of the United States Patent and Trademark Office (“PTO”), the PTO issued United States Patent No. 6,642,245 B1 (“the ‘245 patent”), titled “ANTIVIRAL ACTIVITY AND RESOLUTION OF 2-HYDROXYMETHYL-5-(5-FLUOROCYTOSIN-1-YL)-1,3-OXATHIOLANE,” on or about November 4, 2003. Lupin also admits that what purports to be a copy of the ‘245 patent is attached to the Complaint as Exhibit A. Lupin also admits that the electronic version of FDA’s Orange Book lists information on the ‘245 patent in connection with NDA No. 21-937 for Atripla[®] (efavirenz; emtricitabine; tenofovir disoproxil fumarate) tablets. Lupin expressly denies that the ‘245 patent was “duly and legally issued,” and further denies all remaining allegations in Paragraph 16.

17. Paragraph 17 of the Complaint contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Lupin admits that, according to the electronic records of the PTO, the PTO issued United States Patent No. 6,703,396 B1 (“the ‘396 patent”), titled “METHOD OF RESOLUTION AND ANTIVIRAL ACTIVITY OF 1,3-OXATHIOLANE NUCLESOSIDE [sic] ENANTIOMERS,” on or about March 9, 2004. Lupin also admits that what purports to be a copy of the ‘396 patent is attached to the Complaint as Exhibit B. Lupin also admits that the electronic version of FDA’s Orange Book lists information on the ‘396 patent in connection with NDA No. 21-937 for Atripla[®] (efavirenz; emtricitabine; tenofovir disoproxil fumarate) tablets. Lupin expressly denies that the ‘396 patent was “duly and legally issued,” and further denies all remaining allegations in Paragraph 17.

18. Paragraph 18 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits only that the current FDA-approved label for Atripla[®] (efavirenz; emtricitabine; tenofovir disoproxil fumarate) tablets lists the molecular formula for emtricitabine as C₈H₁₀FN₃O₃S and the structural formula for emtricitabine as:



Lupin denies the remaining allegations of Paragraph 18.

19. Paragraph 19 of the Complaint contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Lupin admits only that the current FDA-approved label for Atripla[®] (efavirenz; emtricitabine; tenofovir disoproxil fumarate) tablets states the following: “[t]he chemical name for emtricitabine is 5-fluoro-1-(2R,5S)-[2(hydroxymethyl)-1,3-oxathiolan-5-yl]cytosine.” Lupin denies the remaining allegations of Paragraph 19.

20. Paragraph 20 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that the cover pages of the ‘245 and ‘396 patents list Dennis C. Liotta, Raymond F. Schinazi and Woo-Baeg Choi as purported inventors. Lupin denies all remaining allegations of Paragraph 20.

21. Paragraph 21 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits only that the cover pages of the ‘245 and ‘396 patents identify “Emory University” as the purported “Assignee.” Lupin denies all remaining allegations of Paragraph 21.

22. Paragraph 22 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 22, and therefore denies all such allegations.

COUNT 1
U.S. Patent No. 6,642,245

23. Lupin restates and incorporates by reference its responses to the allegations in Paragraphs 1 through 22 of the Complaint as though fully set forth herein.

24. Paragraph 24 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that it has submitted an ANDA to FDA for efavirenz/emtricitabine/tenofovir disoproxil fumarate tablets, 600 mg/200 mg/300mg. Lupin denies all remaining allegations of Paragraph 24.

25. Paragraph 25 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that, in a letter dated June 13, 2014, Lupin provided Gilead Sciences, Inc. and Emory University with the requisite notice of Lupin's ANDA, which seeks FDA approval for efavirenz/emtricitabine/tenofovir disoproxil fumarate tablets, 600 mg/200 mg/300mg mg prior to expiration of the '245 patent, and that Lupin's notice satisfies all statutory and regulatory requirements. Lupin denies all remaining allegations in Paragraph 25.

26. Paragraph 26 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that, in a letter dated June 13, 2014, Lupin provided Gilead Sciences, Inc. and Emory University with the requisite notice of Lupin's ANDA for efavirenz/emtricitabine/tenofovir disoproxil fumarate tablets, 600 mg/200 mg/300mg; that Lupin's ANDA contains a so-called "paragraph IV certification" stating that, in Lupin's

opinion and to the best of its knowledge, the ‘245 patent is invalid, unenforceable and/or not infringed; and that Lupin’s notice satisfies all statutory and regulatory requirements. Lupin denies all remaining allegations of Paragraph 26.

27. Paragraph 27 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that its Notice Letter provides, *inter alia*, the detailed legal and factual bases for Lupin’s “paragraph IV certification,” stating that, in Lupin’s opinion and to the best of its knowledge, the ‘245 patent is invalid, unenforceable and/or not infringed. Lupin denies all remaining allegations of Paragraph 27.

28. Denied.

29. Denied.

30. Denied.

31. Denied.

32. Denied.

33. Denied.

34. Denied.

35. Denied.

COUNT 2
U.S. Patent No. 6,703,396

36. Lupin restates and incorporates by reference its responses to the allegations in Paragraphs 1 through 22 of the Complaint as though fully set forth herein.

37. Paragraph 37 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that it has submitted an ANDA to FDA for efavirenz/emtricitabine/tenofovir disoproxil fumarate tablets, 600 mg/200 mg/300mg. Lupin denies all remaining allegations of Paragraph 37.

38. Paragraph 38 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that, in a letter dated June 13, 2014, Lupin provided Gilead Sciences, Inc. and Emory University with the requisite notice of Lupin's ANDA, which seeks FDA approval for efavirenz/emtricitabine/tenofovir disoproxil fumarate tablets, 600 mg/200 mg/300mg prior to expiration of the '396 patent, and that Lupin's notice satisfies all statutory and regulatory requirements. Lupin denies all remaining allegations of Paragraph 38.

39. Paragraph 39 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that, in a letter dated June 13, 2014, Lupin provided Gilead Sciences, Inc. and Emory University with the requisite notice of Lupin's ANDA for efavirenz/emtricitabine/tenofovir disoproxil fumarate tablets, 600 mg/200 mg/300mg; that Lupin's ANDA contains a so-called "paragraph IV certification" stating that, in Lupin's opinion and to the best of its knowledge, the '396 patent is invalid, unenforceable and/or not infringed; and that Lupin's notice satisfies all statutory and regulatory requirements. Lupin denies all remaining allegations of Paragraph 39.

40. Paragraph 40 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that its Notice Letter provides, *inter alia*, the detailed legal and factual bases for Lupin's "paragraph IV certification," stating that, in Lupin's opinion and to the best of its knowledge, the '396 patent is invalid, unenforceable and/or not infringed. Lupin denies all remaining allegations of Paragraph 40.

41. Denied.

42. Denied.

43. Denied.

44. Denied.

45. Denied.

46. Denied.

47. Denied.

* * *

48. Denied.

* * *

The “WHEREFORE” paragraph and subparagraphs (a) through (r) thereof set forth the relief that Plaintiffs seeks through this action, as to which no answer is required. Furthermore, Lupin denies all allegations and statements not expressly admitted or responded to herein. Lupin further denies that Plaintiffs are entitled to any of the relief requested, or to any relief at all, and respectfully requests that the Court:

- a. dismiss this action with prejudice;
- b. enter judgment in favor of Lupin;
- c. award Lupin its reasonable attorneys’ fees and the costs of defending this action and prosecuting its counterclaims according to 35 U.S.C. § 285; and
- d. award Lupin such other and further relief as the Court deems just and appropriate.

[REST OF PAGE INTENTIONALLY BLANK]

SEPARATE DEFENSES

Without prejudice to the denials set forth in the Answer, without admitting any allegation or statement in the Complaint not otherwise admitted, and without undertaking any of the burdens imposed by law on Plaintiffs, Lupin asserts the following separate defenses:

First Defense

The Complaint fails to state a claim upon which relief may be granted.

Second Defense

This Court lacks subject matter jurisdiction over any claims asserted under 35 U.S.C. § 271(a), (b) and/or (c).

Third Defense

This Court lacks subject matter jurisdiction because there is no case or controversy as to invalid and/or unenforceable patent claims.

Fourth Defense

The manufacture, use, sale, offer for sale, or importation of the efavirenz/emtricitabine/tenofovir disoproxil fumarate product that is the subject of Lupin's ANDA has not infringed, does not infringe, and would not – if made, used, sold, offered for sale, imported, or marketed – infringe, either directly or indirectly, any valid and/or enforceable claim of the '245 or '396 patents, either literally or under the doctrine of equivalents.

Fifth Defense

Lupin has not induced, does not induce, and will not induce infringement of any valid and/or enforceable claim of the '245 or '396 patents.

Sixth Defense

Lupin has not contributed, does not contribute, and will not contribute to infringement of any valid and/or enforceable claim of the '245 or '396 patents.

Seventh Defense

The claims of the '245 or '396 patents are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code.

Eighth Defense

The Complaint fails to state a claim for an exceptional case and/or a claim for willful infringement.

Ninth Defense

Any additional defenses or counterclaims that discovery may reveal, including but not limited to additional grounds for unenforceability.

* * *

COUNTERCLAIMS

Defendant/Counterclaim-Plaintiff Lupin Ltd. (“Lupin”) asserts the following counterclaims against Plaintiffs/Counterclaim-Defendants Gilead Sciences, Inc. (“Gilead”) and Emory University (“Emory”) (collectively, “Plaintiffs/Counterclaim-Defendants”).

Parties

1. Lupin is a corporation organized and existing under the laws of the Republic of India, having a place of business at B/4 Laxmi Towers, Bandra Kurla Complex, Bandra (E), Mumbai 400 051, India.

2. On information and belief, Gilead Sciences, Inc. purports to be a corporation organized and existing under the laws of Delaware, also having a place of business at 333 Lakeside Drive, Foster City, California 94404.

3. On information and belief, Emory University purports to be a non-profit corporation of the State of Georgia, having an office at 201 Dowman Drive, Atlanta, Georgia 30322.

Jurisdiction and Venue

4. These Counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

5. This Court has original jurisdiction over the subject matter of these Counterclaims under 28 U.S.C. §§ 1331 and 1338(a).

6. This Court has personal jurisdiction over the Plaintiffs/Counterclaim-Defendants because they have availed themselves of the rights and privileges of this forum by suing Lupin in this District, and because they conduct substantial business in, and have regular and systematic contacts with, this District.

7. Venue is proper in this District under 28 U.S.C. §§ 1391(b), (c) and 1400(b).

Patents-in-Suit

8. On or about November 4, 2003, the United States Patent and Trademark Office issued U.S. Patent No. 6,642,245 B1 (“the ‘245 patent”), entitled “ANTIVIRAL ACTIVITY AND RESOLUTION OF 2-HYDROXYMETHYL-5-(5-FLUOROCYTOSIN-1-YL)-1,3-OXATHIOLANE,” to Dennis C. Liotta, Raymond F. Schinazi, and Woo-Baeg Choi.

9. Plaintiffs/Counterclaim-Defendants purport and claim to have ownership of, and/or the right to enforce, the ‘245 patent.

10. On or about March 9, 2004, the United States Patent and Trademark Office issued U.S. Patent No. 6,703,396 B1 (“the ‘396 patent”) entitled “METHOD OF RESOLUTION AND ANTIVIRAL ACTIVITY OF 1,3-OXATHIOLANE NUCLEOSIDE [sic] ENANTIOMERS,” to Dennis C. Liotta, Raymond F. Schinazi, and Woo-Baeg Choi.

11. Plaintiffs/Counterclaim-Defendants purport and claim to have ownership of, and/or the right to enforce, the ‘396 patent.

12. On or about July 16, 2014, Plaintiffs/Counterclaim-Defendants sued Lupin in this District alleging infringement of the ‘245 and ‘396 patents.

COUNT I
(Declaratory Judgment of Non-Infringement of the ‘245 Patent)

13. Lupin re-asserts and re-alleges each of the foregoing paragraphs as if fully set forth herein.

14. There is an actual, substantial, and continuing justiciable case or controversy between Lupin and Plaintiff/Counterclaim-Defendant regarding non-infringement of the ‘245 patent.

15. The manufacture, use, sale, offer for sale, or importation of the efavirenz/emtricitabine/tenofovir disoproxil fumarate product that is the subject of Lupin's ANDA has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '245 patent, either directly or indirectly.

16. Lupin is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, or importation of the efavirenz/emtricitabine/tenofovir disoproxil fumarate product that is the subject of Lupin's ANDA has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '245 patent, either directly or indirectly.

COUNT II
(Declaratory Judgment of Invalidity of the '245 Patent)

17. Lupin re-asserts and re-alleges each of the foregoing paragraphs as if fully set forth herein.

18. There is an actual, substantial, and continuing justiciable case or controversy between Lupin and Plaintiffs/Counterclaim-Defendants regarding invalidity of the '245 patent.

19. The claims of the '245 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code.

20. Lupin is entitled to a judicial declaration that the claims of the '245 patent are invalid.

COUNT III
(Declaratory Judgment of Non-Infringement of the '396 Patent)

21. Lupin re-asserts and re-alleges each of the foregoing paragraphs as if fully set forth herein.

22. There is an actual, substantial, and continuing justiciable case or controversy between Lupin and Plaintiffs/Counterclaim-Defendants regarding non-infringement of the '396 patent.

23. The manufacture, use, sale, offer for sale, or importation of the efavirenz/emtricitabine/tenofovir disoproxil fumarate product that is the subject of Lupin's ANDA has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '396 patent, either directly or indirectly.

24. Lupin is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, or importation of the efavirenz/emtricitabine/tenofovir disoproxil fumarate product that is the subject of Lupin's ANDA has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '396 patent, either directly or indirectly.

COUNT IV
(Declaratory Judgment of Invalidity of the '396 Patent)

25. Lupin re-asserts and re-alleges each of the foregoing paragraphs as if fully set forth herein.

26. There is an actual, substantial, and continuing justiciable case or controversy between Lupin and Plaintiffs/Counterclaim-Defendants regarding invalidity of the '396 patent.

27. The claims of the '396 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code.

28. Lupin is entitled to a judicial declaration that the claims of the '396 patent are invalid.

PRAYER FOR RELIEF

WHEREFORE, Lupin respectfully prays for judgment in its favor and against Plaintiffs/Counterclaim-Defendants:

- a. declaring that the manufacture, use, sale, offer for sale, or importation of the efavirenz/emtricitabine/tenofovir disoproxil fumarate product that is the subject of Lupin's ANDA has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '245 and '396 patents either directly or indirectly;

- b. declaring the claims of the '245 and '396 patents invalid;
- c. ordering that Plaintiffs/Counterclaim-Defendants' complaint be dismissed with prejudice and judgment entered in favor of Lupin;
- d. declaring this case exceptional and awarding Lupin reasonable attorney's fees and costs under 35 U.S.C. § 285; and
- e. awarding Lupin such other and further relief as the Court may deem just and proper.

DEMAND FOR JURY TRIAL

Lupin hereby demands a trial by jury on all issues so triable.

Dated: August 22, 2014

Respectfully submitted,

LUPIN LTD.

/s/-----
Neil A. Goldberg
Jill C. Owens (JO-3487)
Goldberg Segalla LLP
780 Third Avenue / Suite 3100
New York, New York 10017
(Tel: (646) 292-8700
Fax: (646) 292-8701

Attorneys for Lupin Ltd.

Of Counsel

William A. Rakoczy
Deanne M. Mazzochi
Peter J. Curtin
Jeffrey Marx
RAKOCZY MOLINO MAZZOCHI SIWIK LLP
6 West Hubbard Street, Suite 500
Chicago, Illinois 60654
Telephone: 312-222-6301
Facsimile: 312-222-6321
wrakoczy@rmmslegal.com

Counsel for Lupin Ltd.